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WRITTEN STATEMENT FOR THE

FEDERAL COORDINATING COUNCIL ON COMPARATIVE EFFECTIVENESS RESEARCH

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Good afternoon CE Coordinating Council members and guests. I am Carole Magoffin, current President and CEO of the non-profit Health Quality Institutes of America. I founded HQIA in 1996 as a successor organization to the Center for Clinical Quality Evaluation (CCQE), formerly American Medical Review Research Center (AMRRC) for which I was Founding Executive Director for over a decade, in partnership with leading quality evaluation scientists and quality improvement leaders.

The journey to value-based health care, health status improvement and well being, as well as improved medical outcomes for patients is, to put it mildly, strewn with the bodies and casualties of many failed attempts to rein in costs while improving health and medical delivery quality. Many of us here have worked together to improve health care quality and reduce costs for over twenty five years. I could not be more excited to see the dawn of investing in our collective productivity through health care. "Fixing" a broken system (health and medical) is our shared priority, having presided over our collective failure to reduce widening disparities in this country. We've all witnessed, all too often, the impact of disaggregated, retrospective payment systems and their perverse and contradictory incentives, "look-back" analysis and the absence of effective health, public health and medical care surveillance systems.

I incorporated HQIA as the successor to previous CCQE/AMRRC organizations to form a non-partisan, objective collaborative for guiding advances in value-based purchasing. HQIA supports a health and medical outcome surveillance system designed to promote improved, patient-centered quality care through innovative, population-based health status measurement and geographic surveillance. HQIA supports the application of measures and standards of evidence appropriately adapted for all citizens and sub-populations.

We live in interesting times, where opportunities for innovation abound. There are, however, trends developing on separate tracks that could lead the public debate to a place where our only choices appear to be mutually exclusive -- e.g. lower cost, lower quality care The challenge balance. These major trends need not "derail" one another.

TREND #1: "Keep it simple stupid." One track for comparative effectiveness research and subsequent measure development is the rapidly moving train that calls increasingly understandable, translatable, implementable solutions. This has permitted pilots whereby reimbursement is linked to "best physician or hospital practice" performance with incentives based upon available evidence. This trend falls within the concept of: "not letting the perfect be the enemy of the good." This has allowed commitments from major stakeholders over the past five years that spurred quality measurement advances beyond the wildest held dreams fifteen years ago, when most said the quality of medical care could not be measured, least of all population health and patient-centered health outcomes. Still, the earliest measurement systems developed in the '90's proved daunting for common use by physicians and providers in a world of paper-based (at best) clinical medical records. [I know as I led the first quasi-experimental research to translate clinical guideline evidence into performance measures, as did RAND and other leading measure developers to follow.

In the final analysis, health plans develop simplified, efficient parameters into criteria statements based on what they felt was the strongest evidence available. These statements (e.g. Was a paper smear done? Or percent of women who had a pap smear) could be used with claims data and over time won the day. Specialty societies now lead development of clinical guidelines and measurement tools for conditions they treat. AHRQ and health insurance plans coordinate the major clearinghouse of guidelines and measures. The National Quality Forum and other partnerships like the Ambulatory Quality Alliance, Hospital Quality Alliance, Pharmaceutical Quality Alliance (and the little know Patient-Centered Quality Alliance) endorse measurement tools through a widely approved, highly credible consensus process.

Health information technology leaders [eHealth Initiative, Markel Foundation, National e-Health Collaborative, HIMMS and many others] have labored to develop uniform and interoperable IT standards and measures for close to a decade. Pharmaceutical leaders evolved in their support of generic medications as well as comparative effectiveness research as a means of comparing a range of treatment effectiveness for chronic diseases. (primary care, primary care plus medication, hospital care).

However, as we have learned, simplicity isn't always that simple. Over time, issues have developed over measures that do not have the support of adequate evidence for entire populations. Decisions nodes lack sufficient key patient characteristic data, exceptions and exclusions that can impact as much as two thirds of the population. Remember the pap smear question? For a physician with an older caseload – many women will not have a uterus. We have begun to treat variation in practice patterns, and reducing variations as a causal factor instead of the symptom it truly represents.

TREND #2: Personalized, patient-centered health promoting medical care**.**

Another train is moving on a different track toward genomics, proteomics and personalized, health promoting medical care treatment. Some say this is all too far in the future, yet the developments continue to surprise us all. Business models have yet to be developed to accommodate this radically different approach to workforce health improvement. People are pressing to know whether they are at risk for certain illnesses and medical complications or about the effectiveness and safety of life affirming or life saving therapies and tests. In theory, this more complex model could be the underpinning of future health and medical care, dramatically reducing waste and conserving needed resources as the patient gets precisely the safest, highest quality care based upon clinical evidence stored in his or her electronic medical record.

We have arrived at a juncture in health care where difficult choices are to be made. However, the choice between the supposed simplicity of payer and provider driven evidence versus the supposedly more complex patient-driven evidence is a false choice.

We need to proceed along both tracks in a coordinated way. The decisions that must be made relate more to the proper balance, not either or. Health IT must be part of both journey's in order to meld the best of both worlds. It is this "melding" for which resources must be preserved. We can do complex and simple, as long as the comparative effectiveness research design that develops over time incorporates the decisions logic patients and providers make every day for a host of conditions being treated. It's almost never just diabetes, just CHF or just depression or bipolar disease. Assessing the evidence in relationship to the whole patient must be the priority.

In other words, the truth about comparative effectiveness is somewhere in between the extremes of trends for both simplified and detailed information derived from CER and applied by users. For example, if old and new treatments have the same clinical impact, but vary dramatically in tolerable side-effects – all evidence is relevant. This will always complicate our findings but is the key to developing true value-based systems. New models for conducting clinical trial and quasi-experimental research are needed. Nonetheless, the "train yards" as well as each of the "train cars" for these two approaches need retrofitting to new realities. The "hard lessons" of the past twenty years, are that we risk having arrived at a place in time where out "go to" systems can become "anachronistic" -- not serving the patients, the general population, the public health system, or medical care providers and clinicians.

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